REMARKS

Rejection under 35 USC § 103

The Examiner continues to reject Claims 1 and 5 under 35 USC § 103 as being unpatentable over Grey. Applicant has disagreed with this rejection because:

1. Applicant finds no basis for the Examiner's conclusion that fibromyalgia is "analogous" to the conditions mentioned in Grey. No portion of Grey is cited as warranting such a conclusion. The Examiner responds that "the term 'fibromyalgia' is considered to be a broad term that encompasses muscle and joint pain as treated in the Grey patent." This is an unsupported conclusion.

The Grey patent was filed in 1993 and issued in 1995. Thirteen years later, the medical profession is still of the opinion that the come of fibromyalgia is not known and that the treatment of fibromyalgia combines patient education, stress reduction, regular exercise and medications (see attached "Fibromyalgia" article from MedicineNet.com which was electronically revised on 7/2/2007). Stimulation of deep layered muscle contractions is not mentioned in prior art references or materials.

Grey asserts its usefulness to be in "techniques for post-trauma pain relief and healing" (col 1, ln 17-18). As seen in Figure 1 of Grey, for convenience copied below, cooperating electrodes 14 (col 5, ln 19-22) permanently located in an elastic housing 12 (col 12, ln 53-56) are positioned a short distance apart on the same side of the anatomical structure (Fig 1).

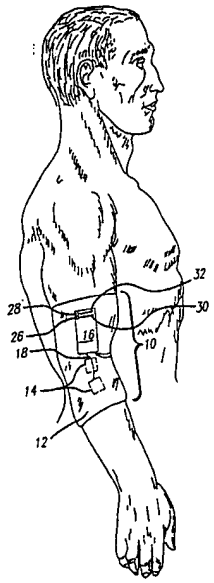

FIG. 1

Therefore, Grey treats neither fibromyalgia nor any other condition in the claimed manner. Applicant's claims 1 and 5 require "sandwiching the tissue surrounding the identified articular joint between one or more pairs of opposed emitter pads" (claim 1, ln 5-6), not positioning a pair of pads on the same side of a joint as in Grey. Furthermore, Applicant claims "applying a biphasic pulse sequence to the pairs of emitter pads to stimulate deep layered muscle contractions in the sandwiched tissue" (claim 1, ln 7-8). Grey has no such teaching and cannot be so applied because of the positioning of Grey's pairs of electrodes.

2. The Examiner also argues that "the ordinarily skilled artisan would appreciate the common sensical notion that the electrodes can be placed in a variety of locations, depending on patient response to treatment."

Grey treats post-trauma injuries with surface therapy. Applicant treats fibromyalgia with deep layered muscle contractions. The ordinarily skilled artisan, based on Grey, has learned nothing that suggests, or is capable of, treating fibromyalgia.

3. Finally, the Examiner argues that "the ordinary artisan would be well aware that square waves have been found to be useful in the treatment of a variety of patient conditions, including pain, and that the pulses shown in Grey are approximations of square waves resulting from capacitor discharge." But Grey teaches nothing that would lead an ordinary artisan to treat fibromyalgia or to use electrical pulses to treat fibromyalgia. Moreover, Applicant's invention treats fibromyalgia, not pain. Grey treats traumatic injuries. There is no teaching in Grey that would cause an ordinary artisan to treat fibromyalgia by use of opposed electrodes to cause deep layered contractions in a sandwiched joint.

CONCLUSION

Applicant claims 1 and 5 are not unpatentable over Grey. Allowance of claims 1 and 5 and issuance of Notice of Allowance are respectfully requested.

The Director is hereby authorized to charge any additional fees or credit any overpayments with regard to this paper to Deposit Account No. 50-1971 per 37 C.F.R. § 1.25.

Respectfully submitted,

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Frank J. Catalano Date
Registration No. 25,836
PTO Customer No. 28827
GableGotwals
100 West 5th St., 10th Floor
Tulsa, OK 74103
Tel: (918) 595-4963
Fax: (918) 595-4990
E-mail: *iplaw@gablelaw.com*

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Fibromyalgia (Fibrositis)

Medical Author: William C. Shiel Jr., MD, FACP, FACR

What is fibromyalgia?

Fibromyalgia is a chronic condition causing pain, stiffness, and tenderness of the muscles, tendons, and joints. Fibromyalgia is also characterized by restless sleep, awakening feeling tired, fatigue, anxiety, depression, and disturbances in bowel function. Fibromyalgia was formerly known as fibrositis.

While fibromyalgia is one of the most common diseases affecting the muscles, its cause is currently unknown. The painful tissues involved are not accompanied by tissue inflammation. Therefore, despite potentially disabling body pain, patients with fibromyalgia do not develop body damage or deformity. Fibromyalgia also does not cause damage to internal body organs. Therefore, fibromyalgia is different from many other rheumatic conditions (such as rheumatoid arthritis, systemic lupus, and polymyositis). In those diseases, tissue inflammation is the major cause of pain, stiffness and tenderness of the joints, tendons and muscles, and it can lead to joint deformity and damage to the internal organs or muscles.

What causes fibromyalgia?

The cause of fibromyalgia is not known. Patients experience pain in response to stimuli that are normally not perceived as painful. Researchers have found elevated levels of a nerve chemical signal, called substance P, and nerve growth factor in the spinal fluid of fibromyalgia patients. The brain nerve chemical serotonin is also relatively low in patients with fibromyalgia. Studies of pain in fibromyalgia have suggested that the central nervous system (brain) may be somehow supersensitive. Scientists note that there seems to be a diffuse disturbance of pain perception in patients with fibromyalgia.

Also, patients with fibromyalgia have impaired non-Rapid-Eye-Movement, or non-REM, sleep phase (which likely explains the common feature of waking up fatigued and unrefreshed in these patients). The onset of fibromyalgia has been associated with psychological distress, trauma, and infection.

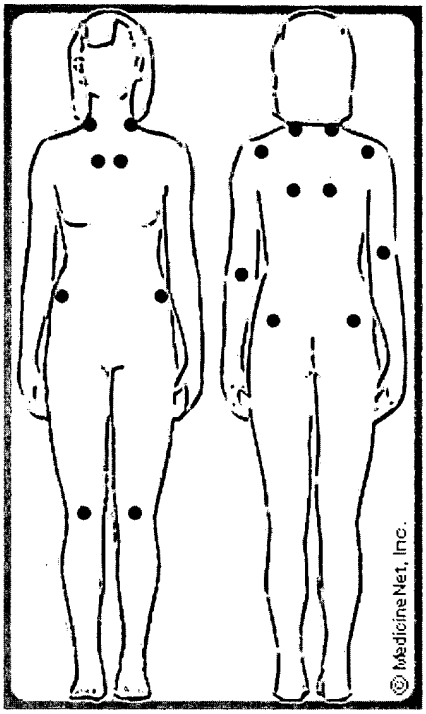
Who does fibromyalgia affect?

Fibromyalgia affects predominantly women (over 80 percent) between the ages of 35 and 55. Rarely, fibromyalgia can also affect men, children, and the elderly. It can occur independently, or can be associated with another disease, such as systemic lupus or rheumatoid arthritis. The prevalence of fibromyalgia varies in different countries. In Sweden and Britain, 1 percent of the population is affected by fibromyalgia. In the United States, approximately 2 percent of the population have fibromyalgia.

What are symptoms of fibromyalgia?

The universal symptom of fibromyalgia is pain. As mentioned earlier, the pain in fibromyalgia is not caused by tissue inflammation. Instead, these patients seem to have an increased sensitivity to many different sensory stimuli, and an unusually low pain threshold. Minor sensory stimuli that ordinarily would not cause pain in individuals can cause disabling pain in patients with fibromyalgia. The body pain of fibromyalgia can be aggravated by noise, weather change, and emotional stress.

The pain of fibromyalgia is generally widespread, involving both sides of the body. Pain usually affects the neck, buttocks, shoulders, arms, the upper back, and the chest. "Tender points" are localized tender areas of the body that can bring on widespread pain and muscle spasm when touched. Tender points are commonly found around the elbows, shoulders, knees, hips, back of the head, and the sides of the breast bone.



Tender Points of Fibromyalgia

Fatigue occurs in 90 percent of patients. Fatigue may be related to abnormal sleep patterns commonly observed in these patients. Normally, there are several levels of depth of sleep. Getting enough of the deeper levels of sleep may be more important in refreshing a person than the total number of hours of sleep. Patients with fibromyalgia lack the deep, restorative level of sleep, called "non-rapid-eye- movement" (non-REM) sleep. Consequently, patients with fibromyalgia often awaken in the morning without feeling fully rested. Some patients awaken with muscle aches or a sensation of muscle fatigue as if they had been "working out" all night!

Mental and/or emotional disturbances occur in over half of fibromyalgia patients. These symptoms include poor concentration, forgetfulness, mood changes, irritability, depression, and anxiety. Since a firm diagnosis of fibromyalgia is difficult, and no confirmatory laboratory tests are available, patients with fibromyalgia are often misdiagnosed as having depression as their primary underlying problem.

Other symptoms of fibromyalgia include migraine and tension headaches, numbness or tingling of different parts of the body, abdominal pain related to irritable bowel syndrome ("spastic colon"), and irritable bladder, causing painful and frequent urination. Like fibromyalgia, irritable bowel syndrome can cause chronic abdominal pain and other bowel disturbances without detectable inflammation of the stomach or the intestines. For further information, please see the read the Irritable Bowel Syndrome article.

Each patient with fibromyalgia is unique. Any of the above symptoms can occur

intermittently and in different combinations.

How is fibromyalgia diagnosed?

There is no blood or x-ray test to help the doctor determine whether someone has fibromyalgia. Therefore, the diagnosis of fibromyalgia is made purely on clinical grounds based on the doctor's history and physical examination. In patients with widespread body pain, the diagnosis of fibromyalgia can be made by identifying point tenderness areas (typically, patients will have at least 11 of the 18 classic tender points), by finding no accompanying tissue swelling or inflammation, and by excluding other medical conditions that can mimic fibromyalgia. Many medical conditions can cause pain in different areas of the body, mimicking fibromyalgia. These conditions include:

- low thyroid hormone level (hypothyroidism)
- parathyroid disease (causing elevated blood calcium level)
- muscle diseases causing muscle pain (such as polymyositis)
- bone diseases causing bone pain (such as Paget's disease)
- elevated blood calcium (hypercalcemia)
- infectious diseases (such as hepatitis, Epstein Barr virus, AIDS)
- cancer

Even though there is no blood test for fibromyalgia, blood tests are important to exclude other medical conditions. Therefore, thyroid hormone and calcium blood levels are obtained to exclude hypercalcemia, hyperparathyroidism and hypothyroidism. The blood alkaline phosphatase (a bone enzyme) level is often raised in patients with Paget's disease of the bone. The CPK (a muscle enzyme) level is often elevated in patients with polymyositis, a disease with diffuse muscle inflammation. Therefore, obtaining alkaline phosphatase and CPK blood levels can help the doctor decide whether Paget's disease and polymyositis are the causes of bone and muscle pains. A complete blood count (CBC), and liver tests help in the diagnosis of hepatitis and other infections.

Fibromyalgia can occur alone, or in association with other systemic rheumatic conditions. Systemic rheumatic conditions refer to diseases that can cause inflammation and damage to numerous different tissues and organs in the body. Systemic rheumatic conditions associated with fibromyalgia include systemic lupus erythematosus, rheumatoid arthritis, polymyositis, and polymyalgia rheumatica. Blood tests which are helpful in evaluating these diseases include erythrocyte sedimentation rate (ESR), serum protein electrophoresis (SPEP), antinuclear antibody (ANA), and rheumatoid factor (RF). In patients with fibromyalgia without associated systemic illnesses, the ESR, SPEP, ANA, and RF blood tests are usually normal.

What is the treatment for fibromyalgia?

Since the symptoms of fibromyalgia are diverse and vary among patients, treatment programs must be individualized for each patient. Treatment programs

are most effective when they combine patient education, stress reduction, regular exercise, and medications. Recent studies have verified that the best outcome for each patient results from a combination of approaches that involves the patient in customization of the treatment plan.

Patient Education

Patient education is an important first step in helping patients understand and cope with the diverse symptoms. Unfortunately, not all physicians are intimately acquainted with the vagaries of this illness. Therefore, community hospital support groups and the local chapters of the Arthritis Foundation have become important educational resources for patients and their doctors. Arthritis Foundation is a national voluntary health organization that provides community education through their many local chapters. Community hospital support groups also provide an arena for patients to share their experiences and treatment successes and failures.

Stress Reduction

It is extremely difficult to measure stress levels in different patients. For some people, spilling milk on the table can represent a significant tragedy. For others, a tank rolling into the living room might represent "just another day!" Therefore, stress reduction in the treatment of fibromyalgia must be individualized. Stress reduction might include simple stress modification at home or work, biofeedback, relaxation tapes, psychological counseling, and/or support among family members, friends, and doctors. Sometimes, changes in environmental factors (such as noise, temperature, and weather exposure) can exacerbate the symptoms of fibromyalgia, and these factors need to be modified.

Exercise

Low-impact aerobic exercises, such as swimming, cycling, walking and stationary cross-country ski machines can be effective treatments for fibromyalgia. Exercise regimens are most beneficial when performed on an every-other-day basis, in the morning. How exercise benefits fibromyalgia is unknown. Exercise may exert its beneficial effect by promoting a deep level of sleep (non-REM sleep). Similarly, avoiding alcohol and caffeine before bedtime can also help promote a more restful sleep.

Medications

Traditionally, the most effective medications in the treatment of fibromyalgia have been the tricyclic antidepressants, medications traditionally used in treating depression. In treating fibromyalgia, tricyclic antidepressants are taken at bedtime in doses that are a fraction of those used for treating depression. Tricyclic antidepressants appear to reduce fatigue, relieve muscle pain and spasm, and promote deep restorative sleep in patients with fibromyalgia. Scientists believe that tricyclics work by interfering with a nerve transmitter chemical in the brain called "serotonin." Examples of tricyclic antidepressants commonly used in

treating fibromyalgia include amitriptyline (Elavil) and doxepin (Sinequan).

Studies have shown that adding fluoxetine (Prozac), or related medications, to low dose amitriptyline (Elavil) further reduces muscle pain, anxiety, and depression in patients with fibromyalgia. The combination is also more effective in promoting restful sleep, and improving an overall sense of well-being. These two medications also tend to cancel out certain side effects each can have. Tricyclic medications can cause tiredness and fatigue while fluoxetine can make patients more cheerful and awake. Even more recently, study of patients with resistant fibromyalgia found that lorazepam (Ativan) was helpful in relieving symptoms. Fluoxetine (Prozac) has also been shown to be effective when used alone for some patients with fibromyalgia.

In 2007, pregabalin (Lyrica) became the first medication approved specifically for treating fibromyalgia.

Other Treatments

Local injections of analgesics and/or cortisone medication into the trigger point areas can also be helpful in relieving painful soft tissues, while breaking cycles of pain and muscle spasm. Some studies indicate that the pain-reliever tramadol (Ultram) and tramadol/acetaminophen (Ultracet) may be helpful for the treatment of fibromyalgia pains. The muscle relaxant cyclobenzaprine (Flexeril) has been helpful for reducing pain symptoms and improving sleep.

The nonsteroidal antiinflammatory drugs (NSAIDs), while very helpful in treating other rheumatic conditions, have only a limited value in treating fibromyalgia pain. Narcotic pain relievers and cortisone medications have not been shown to be beneficial in this condition. Narcotics and cortisone medications are avoided because they have not been shown to be beneficial and they have potential adverse side effects, including dependency, when used long-term.

Both biofeedback and electroacupuncture have been used for relief of symptoms with some success. Standard acupuncture was recently reported to be effective in treating some patients with fibromyalgia.

What is in the future for fibromyalgia therapy?

The key to unlocking the mystery of fibromyalgia has yet to be found. Research scientists have been studying numerous viruses as potential causes for fibromyalgia. Identification of an infectious agent or toxin which causes the disease may one day lead to a laboratory test which can help doctors diagnose fibromyalgia. Until further research uncovers the exact cause of the disease, specific treatment aimed at a cure remains unattainable.

New drugs may be developed that block substance P or nerve growth factor to relieve pain of fibromyalgia. Many fibromyalgia patients can be helped by improved patient education, proper exercise, and medications. With ongoing

research, the future will certainly improve for those affected by fibromyalgia.

Recent research has suggested that drugs that block more than one brain nerve transmitter, such as duloxetine (Cymbalta), can be effective in treating fibromyalgia. Duloxetine has been effective in treating depression and relieving pain in persons with depression. Additional research suggests that the drug pregabalin may be helpful by blocking nerve pain in patients with fibromyalgia. More research is underway to evaluate the potential of these new treatments.

Fibromyalgia At A Glance

- Fibromyalgia causes pain, stiffness, and tenderness of muscles, tendons, and joints without detectable inflammation.
- Fibromyalgia does not cause body damage or deformity.
- Fatigue occurs in 90% of patients with fibromyalgia.
- Irritable bowel syndrome can occur with fibromyalgia.
- Sleep disorder is common in patients with fibromyalgia.
- There is no test for the diagnosis of fibromyalgia.
- Fibromyalgia can be associated with other rheumatic conditions.
- Treatment of fibromyalgia is most effective with combinations of education, stress reduction, exercise, and medications.

For further information about fibromyalgia, contact:

Arthritis Foundation
(http://www.arthritis.org/)
P.O Box 19000
Atlanta, Georgia 30326

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